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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	MDL NO. 15-02641-PHX-DGC
This Document Relates to:	
PHARRIS MORGAN, and BILLY C. MORGAN, JR., her husband, Plaintiffs, v. C. R. BARD, INC., a foreign corporation, and BARD PERIPHERAL VASCULAR INC., an Arizona Corporation, Defendants.	CASE NO. CV-15-1925-PHX-DGC **DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S ANSWER AND DEFENSES TO PLAINTIFFS' COMPLAINT AND DEMAND FOR TRIAL BY JURY**

Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV") (collectively "Defendants"), through undersigned counsel, hereby file their answer and defenses to Plaintiffs' Complaint (the "Complaint") as follows:

PARTIES

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 of the Complaint and, on that basis, deny them. To the extent Paragraph 1 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

2. Defendants admit that Bard is a New Jersey corporation that is authorized to do business, and does business, in the State of Texas. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including previously manufacturing the Recovery® Filter and G2® Filter. Defendants deny any remaining allegations contained in Paragraph 2 of the Complaint.

3. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the State of Texas. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademarks Recovery® and G2® Filter Systems. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations contained in Paragraph 3 of the Complaint.

4. Defendants state that paragraph 4 does not make allegations that require a response from Defendants. To the extent a response is required from Defendants, Defendants deny said allegations.

JURISDICTION AND VENUE

5. Defendants do not contest that the injuries and damages alleged within the Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiffs for any amount whatsoever and deny that Plaintiffs have suffered any damages whatsoever. Defendants do not dispute that, based on the facts as alleged by Plaintiffs, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Eastern District of Texas.

6. Defendants do not contest that the injuries and damages alleged within the Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiffs for any amount whatsoever and deny that Plaintiffs have suffered any damages whatsoever. Defendants do not dispute that, based on the facts as alleged by Plaintiffs, which have not been and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Eastern District of Texas.

7. Defendants do not dispute that, based on the facts as alleged by Plaintiffs, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the United States District Court for the Eastern District of Texas. Defendants admit that they are authorized to do business, and do business, in the State of Texas, including the judicial district for the United States District Court for the Eastern District of Texas.

GENERAL FACTUAL ALLEGATIONS

8. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, denies them. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations contained in Paragraph 8 of the Complaint and, on that basis, denies them.

9. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademark G2® Filter Systems. Defendants further admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations contained in Paragraph 9 of the Complaint and, on that basis, denies them.

10. Defendants deny the allegations contained in Paragraph 10 of the Complaint, including all sub-parts thereof.

11. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market or the identity of manufacturers of inferior vena cava filters. Defendants deny any remaining allegations of Paragraph 11 of the Complaint.

12. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants further admit that inferior vena cava filters may be designed for permanent placement, temporary placement, or both. Defendants deny any remaining allegations of Paragraph 12 of the Complaint.

13. Defendants admit that the inferior vena cava is a large vein that receives blood from the lower regions of the body and delivers it to the right atrium of the heart. Defendants further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to human health, including sometimes death. Defendants deny any remaining allegations of Paragraph 13 of the Complaint.

14. Defendants admit that certain people are at an increased risk for the development of deep vein thrombosis and pulmonary embolus, but lack sufficient information to form a belief as to the truth of the allegations as stated regarding the various risk factors which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus deny them. Defendants deny any remaining allegations of Paragraph 14 of the Complaint.

15. Defendants admit that patients at a high risk for developing deep vein thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy, including but not limited to the medications listed in Paragraph 15 of the Complaint. Defendants further admit that inferior vena cava filters may also be used to treat patients who are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants

lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 15 of the Complaint and, on that basis, deny them.

16. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market. Defendants also lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when optional or retrievable filters came to be marketed or the other allegations regarding optional or retrievable filters marketed by other manufacturers. Defendants admit that the Recovery® Filter System, and the subsequent G2® and G2® X Filters, were cleared by the FDA for optional use as retrievable inferior vena cava filters. Defendants deny any remaining allegations contained in paragraph 16 of the Complaint.

17. Defendants admit that the Recovery® Filter was cleared by the FDA for permanent placement on November 27, 2002, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the requirements of Section 510(k) are legal conclusions of law to which no answer is required. Defendants deny any remaining allegations contained in Paragraph 17 of the Complaint, including the allegations contained in Footnote 1.

18. Defendants admit that the Recovery® Filter was cleared by the FDA for retrievable placement on July 25, 2003, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 18 of the Complaint.

19. Defendants deny the allegations contained in Paragraph 19 of the Complaint.

20. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the twelve wires form two levels of filtration for emboli: the legs provide the lower level of filtration, and the arms provide the upper level of filtration. Defendants deny any remaining allegations contained in Paragraph 20 of the Complaint.

21. Defendants admit that a nickel-titanium alloy named Nitinol is used in the manufacture of the Recovery Filter and further admit that Nitinol contains shape memory. However, to the extent Paragraph 21 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

22. Defendants admit that the Recovery® Filter was designed to be inserted endovascularly. Defendants further admit that the Recovery® Filter is designed to be delivered via an introducer sheath, which is included in the delivery system for the device. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 22 of the Complaint regarding the typical practices of physicians, including physician methods for determining successful implantation of the Recovery® Filter and, on that basis, such allegations are denied. Defendants deny any remaining allegations of Paragraph 22 of the Complaint.

23. Defendants deny the allegations contained in Paragraph 23 of the Complaint.

24. Defendants deny the allegations contained in Paragraph 24 of the Complaint.

25. Defendants deny the allegations contained in Paragraph 25 of the Complaint.

26. Defendants admit that there are various well-documented complications that may occur as a result of the fracture and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 26 of the Complaint, including all sub-parts thereof.

27. Defendants deny the allegations contained in Paragraph 27 of the Complaint.

28. Defendants deny the allegations contained in Paragraph 28 of the Complaint.

29. Defendants deny the allegations contained in Paragraph 29 of the Complaint.

30. Defendants admit that there are various well-documented complications that may occur as a result of the fracture and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 30 of the Complaint, including all sub-parts thereof.

31. Defendants deny the allegations contained in Paragraph 31 of the Complaint.

32. Defendants deny the allegations contained in Paragraph 32 of the Complaint.

33. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2® Filter was developed in furtherance of those efforts. Defendants deny the remaining allegations contained in Paragraph 33 of the Complaint.

34. Defendants admit the G2® Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter. Defendants deny any remaining allegations contained in Paragraph 34 of the Complaint.

35. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2® Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations of Paragraph 35 of the Complaint.

36. Defendants deny the allegations contained in Paragraph 36 of the Complaint.

37. Defendants deny the allegations contained in Paragraph 37 of the Complaint.

38. Defendants admit that there are various well-documented complications that may occur as a result of the fracture and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 38 of the Complaint, including all sub-parts thereof.

39. Defendants admit that there are various well-documented complications that may occur as the result of the fracture and/or migration of any inferior vena cava filter. Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations of Paragraph 39 of the Complaint.

40. Defendants admit that there are various well-documented complications that may occur as the result of the fracture and/or migration of any inferior vena cava filter. Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations of Paragraph 40 of the Complaint.

41. Defendants deny the allegations contained in Paragraph 41 of the Complaint.

42. Defendants deny the allegations contained in Paragraph 42 of the Complaint.

43. Defendants deny the allegations contained in Paragraph 43 of the Complaint.

44. Defendants deny the allegations contained in Paragraph 44 of the Complaint, including all sub-parts thereof.

45. Defendants deny the allegations contained in Paragraph 45 of the Complaint.

46. Defendants deny the allegations contained in Paragraph 46 of the Complaint.

47. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 47 of The Complaint and, on that basis, deny them.

48. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, denies them. Defendants deny any remaining allegations of Paragraph 48 of the Complaint.

49. Defendants deny the allegations contained in Paragraph 49 of the Complaint.

50. Defendants deny the allegations contained in Paragraph 50 of the Complaint.

51. Defendants deny the allegations contained in Paragraph 51 of the Complaint.

52. Defendants deny the allegations contained in Paragraph 52 of the Complaint.

53. The allegations contained in Paragraph 53 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 53 of the Complaint.

54. Defendants deny the allegations contained in Paragraph 54 of the Complaint.

55. Defendants deny the allegations contained in Paragraph 55 of the Complaint.

56. Defendants deny the allegations contained in Paragraph 56 of the Complaint.

57. Defendants deny the allegations contained in Paragraph 57 of the Complaint.

FIRST CAUSE OF ACTION

NEGLIGENCE

58. Defendants incorporate by reference their responses to Paragraphs 1-57 of the Complaint as if fully set forth herein.

59. Defendants deny the allegations of Paragraph 59 of The Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks Recovery® and G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks Recovery® and G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 59 of the Complaint.

60. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, denies them. Defendants deny any remaining allegations of Paragraph 60 of the Complaint.

61. The allegations contained in Paragraph 61 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 61 of the Complaint.

62. Defendants deny the allegations contained in Paragraph 62 of the Complaint.

63. Defendants deny the allegations contained in Paragraph 63 of the Complaint, including all sub-parts thereof.

64. Defendants deny the allegations contained in Paragraph 64 of the Complaint.

65. Defendants deny the allegations contained in Paragraph 65 of the Complaint.

66. Defendants deny the allegations contained in Paragraph 66 of the Complaint, including all sub-parts thereof.

67. Defendants deny the allegations contained in Paragraph 67 of the Complaint.

68. Defendants deny the allegations contained in Paragraph 68 of the Complaint.

SECOND CAUSE OF ACTION

STRICT LIABILITY FAILURE TO WARN

69. Defendants incorporate by reference their responses to Paragraphs 1-68 of the Complaint as if fully set forth herein.

70. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, denies them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 70 of the Complaint.

71. Defendants deny the allegations contained in Paragraph 71 of the Complaint.

72. The allegations contained in Paragraph 72 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 72 of the Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of the Complaint.

74. Defendants deny the allegations contained in Paragraph 74 of the Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of the Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of the Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of the Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of the Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of the Complaint.

THIRD CAUSE OF ACTION

STRICT LIABILITY DESIGN DEFECTS

80. Defendants incorporate by reference their responses to Paragraphs 1-79 of the Complaint as if fully set forth herein.

81. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 81 of the Complaint.

82. Defendants deny the allegations contained in Paragraph 82 of the Complaint.

83. Defendants deny the allegations contained in Paragraph 83 of the Complaint.

84. Defendants deny the allegations contained in Paragraph 84 of the Complaint.

85. Defendants deny the allegations contained in Paragraph 85 of the Complaint.

86. Defendants deny the allegations contained in Paragraph 86 of the Complaint.

FOURTH CAUSE OF ACTION

STRICT LIABILITY MANUFACTURING DEFECT

87. Defendants incorporate by reference their responses to Paragraphs 1-86 of the Complaint as if fully set forth herein.

88. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, denies them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV

designed, sold, marketed, and distributed filters under the trademark G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 88 of the Complaint.

89. Defendants deny the allegations contained in Paragraph 89 of the Complaint.

90. Defendants deny the allegations contained in Paragraph 90 of the Complaint.

91. Defendants deny the allegations contained in Paragraph 91 of the Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of the Complaint.

FIFTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

93. Defendants incorporate by reference their responses to Paragraphs 1-92 of the Complaint as if fully set forth herein.

94. Defendants deny the allegations contained in Paragraph 94 of The Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter Systems. Defendants deny any remaining allegations contained in Paragraph 94 of the Complaint.

95. Defendants deny the allegations contained in Paragraph 95 of the Complaint.

96. Defendants deny the allegations contained in Paragraph 96 of the Complaint.

97. Defendants deny the allegations contained in Paragraph 97 of the Complaint.

98. Defendants deny the allegations contained in Paragraph 98 of the Complaint, including all sub-parts thereof.

99. Defendants deny the allegations contained in Paragraph 99 of the Complaint.

100. Defendants deny the allegations contained in Paragraph 100 of the Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of the Complaint.

102. Defendants deny the allegations contained in Paragraph 102 of the Complaint.

SIXTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION / CONSUMER FRAUD

103. Defendants incorporate by reference their responses to Paragraphs 1-102 of the Complaint as if fully set forth herein.

104. Defendants deny the allegations contained in Paragraph 104 of the Complaint, including all sub-parts thereof.

105. Defendants deny the allegations contained in Paragraph 105 of the Complaint.

106. Defendants deny the allegations contained in Paragraph 106 of the Complaint.

107. Defendants deny the allegations contained in Paragraph 107 of the Complaint.

108. Defendants deny the allegations contained in Paragraph 108 of the Complaint.

109. Defendants deny the allegations contained in Paragraph 109 of the Complaint.

110. Defendants deny the allegations contained in Paragraph 110 of the Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of the Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of the Complaint.

113. Defendants deny the allegations contained in Paragraph 113 of the Complaint.

SEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM

114. Defendants incorporate by reference their responses to Paragraphs 1-113 of the Complaint as if fully set forth herein.

115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 115 of the Complaint and, on that basis, deny them.

116. Defendants deny the allegations contained in Paragraph 116 of the Complaint.

117. Defendants deny the allegations contained in Paragraph 117 of the Complaint.

118. Defendants deny the allegations contained in Paragraph 118 of the Complaint.

119. Defendants deny the allegations contained in Paragraph 119 of the Complaint.

PUNITIVE DAMAGES ALLEGATIONS

120. Defendants incorporate by reference their responses to Paragraphs 1-119 of the Complaint as if fully set forth herein.

121. Defendants deny the allegations contained in Paragraph 121 of the Complaint.

122. Defendants deny the allegations contained in Paragraph 122 of the Complaint, including all sub-parts thereof.

123. Defendants deny the allegations contained in Paragraph 123 of the Complaint.

124. Defendants deny the allegations contained in Paragraph 124 of the Complaint.

PRAYER FOR DAMAGES

Furthermore, responding to the unnumbered Paragraph under the heading "PRAYER FOR DAMAGES," including sub-parts, beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph and all sub-parts thereof.

125. Defendants deny the partial allegations contained in Paragraph 125 of the Complaint.

126. Defendants deny the partial allegations contained in Paragraph 126 of the Complaint.

Defendants further deny each and every allegation not specifically admitted herein.

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiffs' Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiffs' damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

4. If Plaintiffs have been damaged, which Defendants deny, any recovery by Plaintiffs are barred to the extent Plaintiffs voluntarily exposed themselves to a known risk and/or failed to mitigate their alleged damages. To the extent Plaintiffs have failed to mitigate her alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

5. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiffs.

6. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

7. The conduct of Defendants and the subject product at all times conformed with the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent federal statutes and regulations. Accordingly, Plaintiffs' claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

8. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Defendants are not legally responsible.

9. There was no defect in the product at issue with the result that Plaintiffs are not entitled to recover against Defendants in this cause.

10. If there were any defect in the products – and Defendants deny that there were any defects – nevertheless, there was no causal connection between any alleged defect and the product on the one hand and any damage to Plaintiffs on the other with the result that Plaintiffs are not entitled to recover against Defendants in this cause.

11. Plaintiffs' injuries, losses or damages, if any, were caused by or contributed to by other persons or entities that are severally liable for all or part of Plaintiffs' alleged

injuries, losses or damages. If Defendants are held liable to Plaintiffs, which liability is specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause Plaintiffs' alleged damages.

12. Plaintiffs' claims are barred to the extent that the injuries alleged in the Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a manner not intended by Defendants and over which Defendants had no control.

13. Plaintiffs' claims are barred to the extent that the injuries alleged in the Complaint were caused by a substantial change in the product after leaving the possession, custody, and control of Defendants.

14. Plaintiffs' breach of warranty claims are barred because: (1) Defendants did not make any warranties, express or implied, to Plaintiffs; (2) there was a lack of privity between Defendants and Plaintiffs; and (3) notice of an alleged breach was not given to the seller or Defendants.

15. Plaintiffs' claims for breach of implied warranty must fail because the product was not used for its ordinary purpose.

16. Defendants neither had nor breached any alleged duty to warn with respect to the product, with the result that Plaintiffs are not entitled to recover in this cause.

17. Plaintiffs' claims are barred by Defendants' dissemination of legally adequate warnings and instructions to learned intermediaries.

18. At all relevant times, herein, Plaintiff's physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of the subject product.

19. If Plaintiffs have been damaged, which Defendants deny, the actions of persons or entities for whose conduct Defendants are not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the product and other

independent causes, constitute an intervening and superseding cause of Plaintiffs' alleged damages.

20. To the extent that injuries and damages sustained by Plaintiffs, as alleged in Plaintiffs' Complaint, were caused directly, solely, and proximately by sensitivities, medical conditions, and idiosyncrasies peculiar to Plaintiffs not found in the general public, they were unknown, unknowable, or not reasonably foreseeable to Defendants.

21. Defendants believe, and upon that ground allege, that Plaintiffs were advised of the risks associated with the matters alleged in Plaintiffs' Complaint and knowingly and voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed consent, release, waiver, or comparative fault, this conduct bars in whole or in part the damages that Plaintiffs seek to recover herein.

22. At all relevant times during which the device at issue was designed, developed, manufactured, and sold, the device was reasonably safe and reasonably fit for its intended use, was not defective or unreasonably dangerous, and was accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

23. Plaintiffs' claims are barred because Plaintiffs suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.

24. Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver, estoppel, and/or laches.

25. If Plaintiffs suffered any damages or injuries, which are denied, Defendants state that Plaintiffs' recovery is barred, in whole or in part, or subject to reduction, under the doctrines of contributory and/or comparative negligence.

26. In the further alternative, and only in the event that it is determined that Plaintiffs are entitled to recover against Defendants, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to

Plaintiffs, any other defendants, third-party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom Plaintiffs have settled or may settle in the future.

27. Should Defendants be held liable to Plaintiffs, which liability is specifically denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiffs from all collateral sources.

28. Plaintiffs' claims may be barred, in whole or in part, from seeking recovery against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of claims, and the prohibition on double recovery for the same injury.

29. The injuries and damages allegedly sustained by Plaintiffs may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiffs over which Defendants had no control.

30. The conduct of Defendants and all activities with respect to the subject product have been and are under the supervision of the Federal Food and Drug Administration ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

31. Defendants assert any and all defenses, claims, credits, offsets, or remedies provided by the Restatements (Second and Third) of Torts and reserve the right to amend their Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

32. The device at issue complied with any applicable product safety statute or administrative regulation, and therefore Plaintiffs' defective design and warnings-based claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and comments thereto.

33. Plaintiffs cannot show that any reasonable alternative design would have rendered the G2® Filter inferior vena cava filter device as alleged in Plaintiffs' Complaint to

be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could Defendants have known of any alternative design that may be identified by Plaintiffs.

34. The device at issue was not sold in a defective condition unreasonably dangerous to the user or consumer, and therefore Plaintiffs' claims are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and comparable provisions of the Restatement (Third) of Torts (Products Liability).

35. At all relevant times during which the device at issue was designed, developed, manufactured, and sold, the device was reasonably safe and reasonably fit for its intended use, was not defective or unreasonably dangerous, and was accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

36. Defendants specifically plead all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

37. Plaintiffs' alleged damages, if any, should be apportioned among all parties at fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors Act.

38. No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

39. To the extent the claims asserted in Plaintiffs' Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate Defendants' rights under the Constitution of the United States and analogous provisions of the Texas Constitution.

40. Regarding Plaintiffs' demand for punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*

Group, Inc., 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

41. Plaintiffs' claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and similar provisions of the Texas Constitution, on grounds including the following:

(a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

(c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against Defendants, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

42. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiffs have failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

43. The design complained of in Plaintiffs' Complaint, the alleged defects of the product, and/or any alternative design claimed by Plaintiffs were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the product at issue was designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

44. To the extent the Complaint alleges misrepresentation and fraud, these allegations do not comply with the requisite of particularity under applicable procedural rules and/or law.

45. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiffs are not entitled to the relief demanded in the Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

This 27th day of October 2015.

s/Richard B. North, Jr.
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on October 27, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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